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EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

34-

Office Action Summary**Application No.**

09/936,216

Applicant(s)

DALL, DAVID JAMES

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 9-18 and 20-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4112003; 4122004; 9102001; 3142002
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-8 in the reply filed on May 24, 2004 is acknowledged. The traversal is on the ground(s) that Applicant believes that the single general inventive concept under PCT rule 13.1 shared by each of these claims is that they rely on the discovery that spindle body or spindle-like body proteins from insect viruses can be used to control insect pests. Applicant argues that one embodiment of the claimed invention relates to how these proteins can be delivered to insects through transgenic plants, whereas another relates to feed baits for delivery. Applicant argues that the pending claims share a special technical feature in form of the delivery of proteins to insects (response, page 2, 1st full paragraph). This is not found persuasive because the special technical feature of Group I is a transgenic plant comprising at least one nucleotide sequence encoding one or more spindle body proteins or spindle-like body proteins. Neither the transgenic plant nor the nucleotide sequences are shared with the feed bait compositions of Group II or the method of claim 18. Applicant points out that claim 19 should be in Group I because it is dependent on claim 1 (response, page 1, 1st full paragraph). This aspect of Applicant's argument is found persuasive, and claim 19 is rejoined with claims 1-8.

The requirement is still deemed proper and is therefore made FINAL. Claims 1-8 and 19 are examined in this Office action and non-elected claims 9-18 and 20-22 are withdrawn from consideration.

Information Disclosure Statement

2. The citations of Adams et al., Murphy et al., and Huger et al. in the IDS submitted March 14, 2002 have been lined through because they do not include the date of publication or the name of the publication that the article appears in. The citation of Hukuhara et al. in the same IDS has been lined through only because the same citation appears in, and initialed by the Examiner in, the IDS submitted April 11, 2003.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-8 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1: the recitation “from an insect virus” in line 3 of claim 1 renders the claim indefinite. The recitation does not make clear whether the constituent proteins of the SBs or SBLs are to be encoded by the insect virus. Claim 2 indicates that that the constituent protein can be an ER-specific chaperone BiP protein. However, insect viruses do not encode such proteins. It is therefore unclear whether the recitation, “from” in “from an insect virus” in claim 1 is supposed to limit the proteins to those encoded by insect viruses.

In claim 2: the recitation, “ER-specific chaperone BiP proteins” renders the claim indefinite. If the recitation, “from an insect virus” in claim 1 is supposed to indicate that the

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constituent protein(s) of spindle bodies or spindle-like bodies is to be encoded by an insect virus, then claim 2 is indefinite, as insect viruses do not encode BiP proteins.

In claim 19: the recitation, "biological agent" renders the claim indefinite. It is not clear what agents are encompassed by the recitation. The specification on page 7 only indicates what suitable biological agents "include." However, this is an open definition that does not precisely define what other things can be biological agents in the context of the claimed invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-8 and 19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for plants transformed with a nucleotide sequence encoding an insect viral fusolin or fusolin-like protein that is a constituent of a spindle body or spindle-like body from an insect virus, does not reasonably provide enablement for transgenic plants expressing any other constituent proteins of SBs or SLBs from insect viruses. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn towards any plant transformed with at least one polynucleotide molecule comprising any nucleotide sequence(s) encoding one or more constituent protein(s) of spindle bodies (SBs) or spindle-like bodies (SLBs) from any insect virus, wherein said transformed plant expresses said protein(s) in plant tissue(s) susceptible to damage by feeding insects; or wherein the constituent protein(s) is/are selected from fusolins,

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fusolin-like proteins and ER-specific chaperone BiP proteins; or wherein said plant further expresses an exogenous toxin or other agent that is deleterious to insects; a method of controlling or preventing damage caused to a plant according to claim 1 from feeding insects, comprising applying to said plant any insecticidal chemical or biological agent.

The specification asserts that Entomopoxviruses (EPV) are members of the Poxviridae family of viruses that infect insects. EPV have a double stranded DNA genome and replicate in the cytoplasm of insect cells. EPV form proteinaceous structures known as spindle bodies and spheroids in the cytoplasm of insect cells. This trait distinguishes EPV from other Poxviridae members (page 1). Spheroids occlude large numbers of infectious virions and protect them from detrimental environmental factors such as desiccation and exposure to ultraviolet light (page 1). The major constituent protein of spindle bodies is known as “fusolin” (paragraph bridging pages 1-2). Homologs of fusolin are also known as “gp37,” “37K protein,” and “spindle-like protein (SLP)” (page 2). All fusolin proteins have an absolute conservation of amino acid residues at a number of positions. The function(s) of fusolins and fusolin-like proteins remains a topic of investigation (paragraph bridging pages 2-3). The specification indicates that the prior art teaches that a fusolin was shown to be capable of enhancing the infectivity of a heterologous nuclear polyhedrosis virus. The specification also indicates that Hukuhara et al. (Nature Biotech., Nov. 1999, Vol. 17, pages 1122-1124) teach a similar effect in transgenic rice plants expressing the fusolin (page 3). Hukuhara et al. teach that armyworm larvae feeding on transgenic rice plants transformed with the coding sequence of the “Enhancing Factor (EF)” protein of an armyworm EPV showed increased susceptibility to nucleopolyhedrovirus. Hukuhara et al. teach that EF is a fusolin-like glycoprotein (pages 111-112). The specification

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teaches bioassays in which purified spindle bodies *Heliothis armigera* EPV (HaEPV) and *Dermolepida albobirtum* EPV (DaEPV_{SR}) were incorporated into insect diets and fed to *H. armigera* and *Spodoptera litura* larvae. After seven days, the weight of *H. armigera* larvae fed the spindle-body containing diet was less than that of larvae fed a control diet (pages 12-14; Table 3). *H. armigera* larvae that were fed the spindle-body containing diet for 14 days, or those that were fed the spindle-body containing diet for seven days and a control diet for the subsequent seven days, showed lower weights compared to larvae that were fed the control diet for 14 days (pages 14-15; Table 4). A similar assay conducted with *S. litura* larvae showed no difference in the weights of larvae after 7 days feeding, but that significant differences were apparent after 12 days of feeding. Differences in weight were also observed between larvae continuously fed the spindle-body containing diet for 12 days and those fed the spindle-body containing diet for 7 days followed by 5 days of normal diet (pages 16-17; Table 5). The specification also teaches an experiment in which recombinant HaEPV was produced that did not produce fusolin, as judged by the absence of SBs. *H. armigera* larvae were fed diet containing either the recombinant virus or wild type HaEPV. The wild type virus was substantially more infectious compared to the recombinant virus. The specification also indicates that inspection of the weight of larvae at 7 days shows that in the presence of fusolin, larval weight gain was reduced. The specification also indicates that a lower rate of pupation at 21 days was observed in those larvae fed diet comprising wild type HaEPV versus that fed the recombinant virus (pages 17-19).

A review of claim 1 indicates that it encompasses all plants transformed with at least one polynucleotide molecule comprising a nucleotide sequence(s) encoding any one or more

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constituent protein(s) of SBs or SBLs from any insect virus. The specification cites Hukuhara et al. for its teaching of increased baculovirus susceptibility of armyworm larvae feeding on transgenic rice plants expressing an armyworm fusolin-like protein, as discussed above. However, the specification does not teach the control of insects feeding on plants transformed with any other constituent protein of SBs or SBLs of any insect virus. The prior art is lacking in examples showing the ability of other proteins of SBs or SBLs to inhibit weight gain or development of insect larvae, or to have any deleterious effect on any insect. The instant specification itself teaches that spindle bodies lacking fusolin does not have an effect on insects, as discussed above. The specification also admits that it is fusolin that is responsible for the deleterious effects of feeding, growth and development of insects that consume the spindle bodies (page 3, lines 17-27). In the absence of further guidance, undue experimentation would be required by one skilled in the art to produce plants transformed with nucleotide sequences encoding other proteins of SBs or SBLs of any insect virus, wherein the expressed protein prevents damage to the plant from feeding insects or otherwise controls feeding insects. The specification does not teach how to use plants transformed with proteins of SBs or SBLs wherein damage caused by insects is not prevented or controlled. See Genentech, Inc. v. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention.

Further, regarding claim 2: the claim indicates that the constituent protein may be the ER-specific chaperone BiP. However, parent claim 1 indicates that the proteins are from insect viruses. Neither the prior art nor the specification teaches any virus that encodes an ER-specific chaperone BiP protein. Undue experimentation would be required by one skilled in the art to

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make the claimed plant, as this would involve the discovery of an insect virus that encodes an ER-specific BiP that is a constituent of a SB or SLB, and the isolation of the coding sequence of that BiP. No direction is provided as to what insect viruses may encode a BiP. See Genentech, Inc. v. Novo Nordisk, A/S, supra. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to practice the full scope of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Leborgne-Castel et al. (Plant Cell, March 5, 1999, Vol. 11, pages 459-469), as evidenced by Lai-Fook et al. (J. Invert. Pathol., 2000, Vol. 75, pages 183-192).

The claims are broadly drawn towards any plant transformed with at least one polynucleotide molecule comprising any nucleotide sequence(s) encoding one or more constituent protein(s) of spindle bodies (SBs) or spindle-like bodies (SLBs) from any insect virus, wherein said transformed plant expresses said protein(s) in plant tissue(s) susceptible to damage by feeding insects; or said plant wherein the one or more constituent proteins is/are selected from fusolins, fusolin-like proteins and ER-specific chaperone BiP proteins.

Leborgne-Castel et al. teach transgenic plants overexpressing BiP. The BiP coding region was operably linked to the constitutive CaMV 35S promoter (pages 460-461). The

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property of being a constituent protein of SBs or SBLs from an insect virus is inherent to BiP proteins, as evidenced by Lai-Fook et al. (page 189). The BiP protein in the transgenic plant taught by Leborgne-Castel et al. is expressed in plant tissues susceptible to damage by feeding insects, given that the BiP coding sequence transcribed by a constitutive promoter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 2, 7, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leborgne-Castel et al. (Plant Cell, March 5, 1999, Vol. 11, pages 459-469) in combination with Adang et al. (Plant Mol. Biol., 1993, Vol. 21, pages 1131-1145).

The claims are broadly drawn towards any plant transformed with at least one polynucleotide molecule comprising any nucleotide sequence(s) encoding one or more constituent protein(s) of spindle bodies (SBs) or spindle-like bodies (SLBs) from any insect virus, wherein said transformed plant expresses said protein(s) in plant tissue(s) susceptible to damage by feeding insects; or said plant wherein the one or more constituent proteins is/are selected from fusolins, fusolin-like proteins and ER-specific chaperone BiP proteins; or wherein said plant further expresses any exogenous toxin or other agent that is deleterious to insects.

Leborgne-Castel et al. is discussed above.

Leborgne-Castel et al. do not teach other exogenous toxins or other agents that are deleterious to insects.

Adang et al. teach the increased insect resistance of transgenic plants expressing the *Bacillus thuringiensis* cryIIIA delta-endotoxin (pages 1140-1142).

It would have been obvious and within the scope of one or ordinary skill in the art at the time the invention was made to also express in the plant of Leborgne-Castel et al. the *B. thuringiensis* delta-endotoxin coding sequence of Adang et al. One would have been motivated to do so to confer further insect resistance to the host plant.

7. Claims 1, 2, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leborgne-Castel et al. (Plant Cell, March 5, 1999, Vol. 11, pages 459-469) in combination with Colliot et al. (U.S. Patent No. 5,877,194).

The claims are broadly drawn towards any plant transformed with at least one polynucleotide molecule comprising any nucleotide sequence(s) encoding one or more constituent protein(s) of spindle bodies (SBs) or spindle-like bodies (SLBs) from any insect virus, wherein said transformed plant expresses said protein(s) in plant tissue(s) susceptible to damage by feeding insects; or said plant wherein the one or more constituent proteins is/are selected from fusolins, fusolin-like proteins and ER-specific chaperone BiP proteins; or a method of controlling or preventing damage caused to said plant from feeding insects, comprising applying to said plant any insecticidal chemical and/or biological agent.

Leborgne-Castel et al. is discussed above.

Leborgne-Castel et al. do not teach insecticidal chemicals.

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Colliot et al. teach a process for protecting plants against insects, comprising the application of an insecticidal compound to plants (claims).

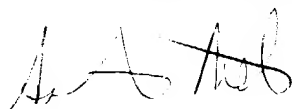
It would have been obvious and within the scope of one of ordinary skill in the art at the time the invention was made to apply to the plant of Leborgne-Castel et al., the insecticidal compound of Colliot et al. One would have been motivated to do so as this would obviously further protect the plant from damage caused by insects.

Contact Information

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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August 5, 2004



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Primary Examiner
Art Unit 1638